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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,475

09/30/2005

Michael George

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EXAMINER

GROSS, CHRISTOPHER M

ART UNIT

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1639

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,475	<b>Applicant(s)</b> GEORGE ET AL.	
	<b>Examiner</b> CHRISTOPHER M. GROSS	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-92 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 47-92 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☒ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Responsive to communications entered 9/18/2008. Claims 47-92 are pending.

#### ***Priority***

This application is a 371 of PCT/GB04/01418 03/31/2004.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to UK patent 0307559.5, filed 04/02/2003. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Acknowledgment is made of applicant's claim for foreign priority based on provisional application 60465807 filed in the United States on 04/28/2003. It is noted, however, that applicant has not filed a certified copy of the US application as required by 35 U.S.C. 119(b).

In view of applicant's extensive amendments to the claims between the international filing date of 3/31/2004 and the national stage entry on 9/30/2005, applicant is required in response to this office action to provide priority dates for each new pending claims 47-92 as well as point out, specified as to page and line, where support under 35 USC 112 first paragraph may be found in the present or earlier applications.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure. See MPEP 714.02, paragraph 5, last sentence and also MPEP 2163.06 I.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 47-58,80-87, drawn to a library of tagged ligands

Group II, claim(s) 47,59-61,71, drawn to a process of preparing a library of tagged ligands.

Group III, claim(s) 47,62-63,69,72-79, drawn to a method of selecting a tagged ligand

Group IV, claim(s) 47,64-68,70,88-91, drawn to a compound of formula I

Group V, claim(s) 92, drawn to a compound of structure set forth therein.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of groups I-V appears to be related to libraries of fluorescently labeled ligands, such as a G-protein coupled receptor (GPCR) ligands.

However, libraries of fluorescently labeled GPCR ligands were known in the art at the time the invention was filed (Fay et al 1991 Biochemistry 30: 5066-5075), therein the technical feature linking all the inventions of groups I-V does not constitute a *special* technical feature as defined by PCT Rule 13.2, because it does not define a contribution over the prior art.

Each compound is patently distinct as is its method of preparation or use. The method of group II may be used to prepare the fluorescently labeled peptide GPCR ligands of Fay et al in addition to the library or individual compounds set forth as inventions I, IV and V. The method of selecting a tagged ligand set forth as invention III requires materially different steps concerning pharmacology, not required for the method of preparation that is invention II. The tagged ligand library set forth as group I may be used for discerning structure activity relationships whereas the compounds set forth as inventions IV and V may be used for measuring absolute affinity constants but not vice versa. The compounds of group IV and V do not share a chemical core. Therefore, unity of invention is lacking from groups I-V.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

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are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Species Election***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Each **genus** identified below is indicated in **bold**. Applicant is requested to elect species from within *each* genus of the elected invention.

(From claims 47-48,50-58,80-87; 59-61,71;62-63; 64-68,70,88,89-91; 92)

Applicant is required to elect single specific species of **fluorescent ligand** specified as atom and bond indicating formula (I, I', etc.), linker(s), fluorophore(s), without the use of variable groups (i.e. Lig; J<sub>L</sub>, etc.) Applicant is to elect using a chemical drawing.

Currently, claims 47-48,50-58,80-87 are generic for invention I; claims 47,59-61,71 are

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generic for invention II; claims 47,62-63 are generic for invention III; claims 47,64-68,70,88,89-91 are generic for invention IV; claim 92 is generic for invention V.

(From claim 52) Applicant is required to elect one single specific species of **GPCR ligand**, as set forth in claim 52. Currently, claims 47,52 are generic for invention I.

(From claims 59-61,71) Applicant is required to elect two specific species of **ligand precursors**, specified as atom and bond, indicating formulas (IV, V', etc.), linker(s), fluorophore(s), without the use of variable groups (i.e. Lig; J<sub>L</sub>; etc.). Applicant is to elect using a chemical drawing. Currently claims 47,59-61,71 are generic for invention II.

(From claim 49) Applicant is required to elect one single specific species of **library type**, as set forth in claim 49. Currently, claims 47,49 are generic for invention I.

(From claims 47,78) Applicant is required to elect one single one specific species of **target** from those set forth in claims 78. Currently, claim 47 is generic for inventions I,II, and IV; claims 47,78 are generic for invention III.

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed sequences, the Markush group shall be regarded as being of similar nature when

(A) all alternatives have a common property or activity **and**

(B)(1) a common structure is preset, i.e., a significant structure is shared by all of the alternatives or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The species listed above are considered to be each separate inventions for the following reasons:

The genus/genera set forth above include species which do not share a common core structure. For example, each of the fluorophores present in the three types of ligands, do not share a common ring configuration and are not expected to have similar activity or properties. While the ligand(s) may be said to share a common property of protein binding, they do not share a common structural element throughout the claimed genus, especially in view of the various library types of claim 49.

The various targets, such as GPCRs, intracellular enzymes and drug transporters do not share a common activity.

(From claim 51) Applicant is required to elect single one specific species of **activity** from those set forth in claim 51. Currently, claims 47,51 are generic for invention I.

Each activity does not share a common technical feature in that each requires materially different steps to measure.



(From claims 73-74) Applicant is required to elect one single one specific species of **pharmacological property** from those set forth in claims 73-74. Currently, claims 47,73-74 are generic for invention III.

Each pharmacological property does not share a common technical feature in that each requires materially different steps to measure.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

**Applicant is to further indicate what functional groups of the elected species of fluorescent ligand correspond to which trade names, chemical names and variables (i.e.  $R_e^{11}$ ;  $Y_{Ligm}$ , etc.) set forth in the readable claims.**

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER M. GROSS whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571 272 0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross  
Examiner  
Art Unit 1639

cg

/ Christopher S. F. Low /  
Supervisory Patent Examiner, Art Unit 1639